IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Myron E. Essex et al.
Serial No. : 056,134
Filed : May 29, 1987
For : ASSAY FOR DETECTING INFECTION BY HTLV-III

Examiner Nucker
Group Art Unit 181

#11

Commissioner of Patents and Trademarks
Washington, DC 20231

DECLARATION OF MYRON E. ESSEX AND TUN-HOU LEE

The undersigned, Myron E. Essex and Tun-Hou Lee, declare,

1. We are the co-inventors of the subject matter claimed in the above-captioned U.S. patent application, and in its parent application U.S.S.N. 670,361, filed November 9, 1984.

2. We have read the Office Action mailed January 11, 1989 as well as the following documents: Montagnier et al., U.S. Patent 4,708,818; Schupbach et al., Science 224:503-505 (1984); and Sangaharen et al., Science 224:168-174 (1984).

3. When we filed the parent U.S. patent application on November 9, 1984, the art was generally confused about the nature and even the existence of the HTLV-III envelope glycoprotein. No one had reported finding or isolating such a protein. This confusion is evidenced by the Montagnier et al. patent filed December 3, 1983 which incorrectly speculates at column 5, lines 14-24, that a protein of about 80,000 m.w. along with 36,000 m.w. and 42,000 m.w. proteins represent the major HTLV-III envelope glycoproteins.

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I hereby certify that this ... deposited with the United States ... first class mail in an envelope addressed to ... sioner of Patents and Trademarks, Washington ... 20231, on 5-11-89
[signature]

4. All the gp120 and gp160 experiments relating reported in Allan et al., Science 228:1091-1094 (1985) and Kitchen et al., Nature 312:367-369 (1984) were performed under our direction and control. Other authors listed on those publications are not co-inventors of the subject matter claimed in this patent application.

5. The Schupbach et al. reference reports a large number of bands on a variety of SDS gels. There is no indication of the nature of the putative band at 110,000 m.w. The focus of the Schupbach et al. reference is on smaller proteins.

6. The 110,000 m.w. band does not appear clearly or consistently in the Schupbach et al. gels. The authors report that the 110,000 m.w. band is detected only in viral lysate, not in cellular lysate. In distinction, our experience as well as the experience of others, is that gp120 generally is detected by cellular lysate.

7. Schupbach et al. mention several smaller bands now known to be associated with HTLV-III (e.g., p. 41 and p. 24). They also mention several bands having no currently known association with HTLV-III (88,000, 80,000 and 39,000).

8. There is no indication as to the nature of the 110,000 band reportedly detected in viral lysate. One skilled in the art would not conclude from the teaching of Schupbach et al. and other information available as of November 9, 1984, that the 110,000 band (whatever it might have been) would be useful in an immunoassay for AIDS antibody.

9. One skilled in the art could obtain a protein which contains a gp120 determinant by the following procedure. First gp120 is isolated as described in the above-captioned application. Then, the gp120 band is subjected to proteolytic cleavage by the general method of Cleveland et al., J. Biol. Chem. 252:1102-1106 (1977) or Snyder, Cold Spring Harbor Symposia On Quantitative Biology, Vol. XLIV, pp. 787-799 (1980). To find gp120 determinant-containing fragments, the resulting fragments are then blotted with sera of AIDS patients, or competition with gp120 is determined as described by Morgan et al., J. Virology 46:177-186 (1983). Routine Edman degradation could be used to sequence those fragments.

10. All statements made herein of our own knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Myron G Essex

Myron E. Essex

Date: April 10, 1989

Tun-Hou Lee

Tun-Hou Lee

Date: April 10, 1989